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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-------------------------|------------------|
| 09/422,528 | 10/21/1999 | WOON-LAM Susan LEUNG | P1190R1 | 5652 |
| 7590 | 02/10/2004 | | EXAMINER | |
| ATTN JANET E HASAK GENENTECH INC 1 DNA WAY SOUTH SAN FRANCISCO, CA 940804990 | | | FRONDA, CHRISTIAN L | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1652 | |
| | | | DATE MAILED: 02/10/2004 | |

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Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/422,528 | LEUNG ET AL. | |
| | Examiner | Art Unit | |
| | Christian L Fronda | 1652 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-25 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-25 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 a) The translation of the foreign language provisional application has been received.
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). 9.
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 and 5. 6) Other: _____.

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DETAILED ACTION

Election/Restriction

1. Applicants' election with traverse of Group I, claims 1-11 and 13-24 is acknowledged. Applicants' position is that the inventions of Groups I-III are not distinct and/or independent since independent claim 1 encompasses both Groups II and III. This is found to be persuasive and the restriction requirement has been withdrawn.

2. Claims 1-25 are under consideration in this Office Action.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are genus claims which encompass any method for making and recovering proteins using any bacterium containing any nucleic acid encoding any phage lysozyme of any structure and sequence and any nucleic acid encoding any desired heterologous polypeptide. The genus claims are expected to be highly variant since nucleic acids encoding any phage lysozyme are expected to substantially differ from each other and that nucleic acids encoding any desired heterologous polypeptide is expected to differ from each other since they encode different proteins of differently biological activities.

The specification provides only a written description for making an IGF-I using a bacterium transformed with plasmid pIGFLysAra containing a nucleotide sequence encoding IGF-I and lamB signal sequence and a nucleotide sequence encoding T4-lysozyme and ara promoter. The plasmid pIGFLysAra is only one representative species of the claimed genus. However, the specification also fails to describe additional representative species encompassed

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by the genus for which predictability of structure and function is not apparent.

The specification does not provide a written description for any nucleic acid encoding any phage lysozyme of any structure and sequence or any nucleic acid encoding any desired heterologous polypeptide. Given the lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

5. Claims 1-25 rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The nucleotide sequence of the pIGFLysAra (SEQ ID NO:) is critical or essential to the practice of the invention, but not included in the claims is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

Furthermore, the claims are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether undue experimentation is required, are summarized *In re Wands* [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompass any method for making and recovering proteins using any bacterium containing any nucleic acid encoding any phage lysozyme of any structure and sequence and any nucleic acid encoding any desired heterologous polypeptide. However, the specification provides guidance for making an IGF-I using a bacterium transformed with plasmid pIGFLysAra containing a nucleotide sequence encoding IGF-I and lamB signal sequence and a nucleotide sequence encoding T4-lysozyme and ara promoter.

While molecular biological techniques and genetic manipulation techniques are known in the prior art and the skill of the artisan are well developed, knowledge regarding the specific nucleotide sequence of the phage lysozyme and whether it can be used in the production of any heterologous polypeptide is lacking. Thus, searching for the nucleotide sequence of the phage lysozyme and whether it can be used in the production of any heterologous polypeptide is well outside the realm of routine experimentation and predictability in the art of success is extremely low.

The amount of experimentation involved in searching for the nucleotide sequence of the phage lysozyme and determining whether it can be used in the production of any heterologous

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polypeptide is undue and is outside the realm of routine experimentation. The Examiner finds that one skilled in the art would require additional guidance, such as information regarding the nucleotide sequence of the phage lysozyme which can be used in the claimed method.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-5, 9-11, 14-19, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Leung et al. (Book of Abstracts, 216th ACS National Meeting, Boston, August 23-27 (1998), BIOT-014. American Chemical Society: Washington, D. C.)

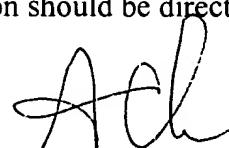
Leung et al. teach the claimed method where an IGF-I is produced by culturing a bacterium containing a nucleic acid encoding IGF-I and T4 lysozyme which is expressed near the end of the fermentation, T4 lysozyme is accumulated in the cytoplasm and released by cell homogenization, and refractile particles recovered in greater amount compared to treatment with EDTA and HEWL (see entire publication). Thus, the reference teachings anticipate the claimed invention.

Conclusion

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (571)272-0929. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571)272-0928. The official fax phone number (703)872-9306. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (571)272-1600.

CLF



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